## (12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization International Bureau





(43) International Publication Date 15 January 2004 (15.01.2004)

PCT

(10) International Publication Number WO 2004/005927 A1

(51) International Patent Classification7: G01N 33/574, C12Q 1/68

(21) International Application Number:

PCT/EP2003/050096

(22) International Filing Date: 8 April 2003 (08.04.2003)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data: 02007954.7

9 April 2002 (09.04.2002)

(71) Applicant (for all designated States except US): MTM LABORATORIES AG [DE/DE]; Im Neuenheimer Feld 583, 69120 Heidelberg (DE).

(72) Inventor; and

(75) Inventor/Applicant (for US only): MARTIN, Peter [DE/DE]; Buchensteige 4, 69251 Gaiberg (DE).

(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN. YU, ZA, ZM, ZW.

(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

## Published:

with international search report

ance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

For two-letter codes and other abbreviations, refer to the "Guid-

(54) Title: METHOD FOR DISCRIMINATION OF METAPLASIAS FROM NEOPLASTIC OR PRENEOPLASTIC LESIONS

(57) Abstract: The present invention relates to a method for discrimination of p16<sup>INK4a</sup> overexpressing metaplasias from neoplastic or preneoplastic p16INK4a overexpressing lesions by determination of the level of high risk HPV encoded gene-products such as e.g. HPV E2 and/or HPV E7 molecules in biological samples in the course of cytological testing procedures. The method thus enables for reduction of false positive results in the p16<sup>INK40</sup> based detection of anogenital lesions in cytological testing procedures.